

REMARKS

Response to “Notice of Non-Compliant Amendment”

The foregoing amendments are presented in the form required by 37 CFR 1.121.

A Petition for Extension of Time under 37 CFR 1.136(a)(1) to respond to the Notice of March 15, 2005 and the petition fee are filed concurrently herewith.

Claim Objections

The Examiner objected to Claim 1 as “containing non-elected subject matter.” In its presently amended form, Claim 1 now reads directly on a composition containing both “**calcium ascorbate**” (a “plasma soluble metal salt of ascorbic acid” as recited in paragraph (a) of Claim) and “**a non-toxic metal salt of an aldonic acid,**” as specifically expressed in paragraph (b) of presently amended Claim (aldonic acids...and non-toxic metal salts of thereof). Accordingly, it is respectfully submitted that Claim 1 should be examined as readable on the elected species.

Claim Rejections – 35 USC §112

Claim is presently amended to insert the Markush group now appearing as paragraph (b) of amended claims 1. Express support for the Markush group is found at the Specification, Page

6, line 19 – Page 7, line 7. Accordingly, it is respectfully submitted that presently amended Claim 1 is fully supported by the original specification. The rejection based on failure to comply with the written description requirement of 35 USC §112 should be withdrawn.

Claim Rejections – 35 USC §103

Claims 1 and 4 were rejected as “obvious” within the meaning of 35 USC §103, based on the combination of *Markham* and *Riordan*.

Markham discloses (Column 2, lines 27-29) the function of the metabolites in his vitamin C-metabolite compositions, disclosing that the **metabolites are**

“necessary to achieve the desired result, **improvement in Vitamin C absorption and or retention..**”

Markham does disclose that his vitamin C-metabolite compositions are better tolerated than prior art Vitamin C, to prevent “diarrhea and other side reactions, such as gastric irritation and inflammation” (Col. 1, lines 60-61) or kidney-stone formation (Col 2, line 63 – Col 3, line 2) , but ***Markham* does not teach that such compositions would be useful in cancer treatment.**

Riordan deals with the selective anti-tumor effect of “AA” (ascorbic acid) rather than “plasma soluble metal salts of ascorbic acid” as in Applicant’s claimed compositions. *Riordan*’s focus is on the selectivity of AA, i.e., the ability to kill cancer cells without killing normal cells. There is no suggestion or even a hint that prevention of diarrhea, gastric inflammation or kidney stone formation would enhance the selectivity of AA in killing cancer cells versus normal cells.

The Claimed Invention

Applicant discovered that his compositions (mineral ascorbate **salt** of AA + metabolites)

achieve minimum two-fold increase in cell death rate, or lower concentrations (AA equivalent) than is required to achieve such decrease with either mineral ascorbate alone or with ascorbic acid alone.

(Specification, pp. 21-22)

This is an astounding and clearly unpredictable result compared to the disclosures of either *Markham* or *Riordan*, taken alone or in combination.

The Examiner is respectfully requested to note that all of the claims now in the case, Claims 1 and 4, are “method” claims, i.e.,

“A selective chemotherapy method which includes the step of contacting tumor cells with (the composition specified in the claim).

This is the entirely appropriate way to claim a new and unobvious use of an old composition.


Double Patenting

The provisional double patenting rejection is noted. An appropriate terminal disclaimer will be filed upon the indication of allowance of the claims of the '912 application.

CONCLUSION

In view of the foregoing amendments and remarks, reconsideration of the objections and rejections stated in the Office Action of September 16 is respectfully requested.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "William H. Drummond". The signature is fluid and cursive, with the first name "William" and last name "Drummond" clearly distinguishable.

William H. Drummond
Attorney for Applicant